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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,456	10/19/2002	Toshio Kawai	20.001-AG	4033
29453	7590	08/28/2006	EXAMINER	
JUDGE & MURAKAMI IP ASSOCIATES DOJIMIA BUILDING, 7TH FLOOR 6-8 NISHITEMMA 2-CHOME, KITA-KU OSAKA-SHI, 530-0047 JAPAN			BABIC, CHRISTOPHER M	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/065,456	<b>Applicant(s)</b> KAWAI, TOSHIO	
	<b>Examiner</b> Christopher M. Babic	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4,6,7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,6,7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 4, 6, 7, and 9-12 are pending. The following Office Action is in response to Applicant's response dated June 9, 2006.

### ***Specification***

The objection of the specification has been withdrawn in view of Applicant's explanation.

### ***Claim Rejections - 35 USC § 103***

It is noted that the rejections of claims 4, 5, and 7-12 over Corbett , and subsequent rejection of claim 6 over Corbett in view of Haff have been withdrawn because, upon further consideration, it was decided that the disclosure of Corbett does not clearly delineate the scientific reasoning upon which the ground(s) of the rejection is based.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**1. Claims 4-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Haff et al. (EP 0 636 413 A2).**

With regard to Claim 4, Haff et al. disclose an apparatus for continuous amplification of DNA (Figure 1; Columns 9-12, for example), comprising: a reaction-mixture tank for holding a reaction mixture containing DNA fragments and a reagent solution (Column 10, Lines 40-55, for example); a denaturing isothermal tank made up of a container body for holding a heat-exchange fluid (Figure 1; Column 10, Lines 1-10, for example), a heating device for heating the heat-exchange fluid to (Column 11, Lines 50-55, for example), and retaining it at, a prescribed temperature for dissolving apart the DNA's double strands, and a stirring device for stirring the heat-exchange fluid (Column 10, Lines 1-10, for example); an annealing isothermal tank made up of a container body for holding a heat-exchange fluid (Figure 1; Column 10, Lines 1-10, for example), a heating device for heating the heat-exchange fluid to (Column 11, Lines 50-55, for example), and retaining it at, a prescribed temperature at which primers contained in the reagent solution anneal to the DNA fragments, a stirring device for stirring the heat-exchange fluid (Column 10, Lines 1-10, for example); an elongation isothermal tank made un of a container body for holding a heat-exchange fluid (Figure 1; Column 10, Lines 1-10, for example), a heating device for heating the heat-exchange fluid to (Column 11, Lines 50-55, for example), and retaining it at, a prescribed temperature at which complementary chains are extended continuously onto the primers, and a stirring device for stirring the heat-exchange fluid (Column 10, Lines 1-10, for example). It is

noted that Figure 1 discloses only two temperature zones, however, Haff et al. expressly discloses that three temperature stable liquid baths may be used for three separate incubation temperatures (Column 9, Lines 30-40, for example).

Haff et al. further discloses a circulation-path system through which the reaction mixture in the reaction-mixture tank is fed and guided, the circulation-path system being arranged such that it circuits from the reaction-mixture tank and goes by way of the denaturing, annealing, and elongation isothermal tanks (Figure 1; Column 10, Lines 25-45, for example); and a pump working to feed the reaction mixture in said circulation-path system unidirectionally through it (Figure 1; Column 15-30, for example); wherein the apparatus is configured such that the reaction mixture in said circulation-path system is for timed intervals maintained at prescribed temperatures determined by the heat-exchange fluids in the isothermal tanks (Column 12, Lines 1-20, for example); and connected by intervening out-of-tank sections (figure 1, 2B, for example).

Haff et al. does not expressly disclose that the *same* reaction mixture is cycled through the temperature zones of the apparatus in Figure 1, however, Haff et al. does disclose one amplification reaction mixture cycled through different temperature zones multiple times in Figure 2.

It would have been *prima facie obvious* to a practitioner of ordinary skill in the art at the time of invention to the flow the same reaction mixture through the apparatus of Figure 1 multiple times since Haff suggests such a modification to continuously amplify the same reaction mixture through multiple amplification cycles.

Haff does not expressly disclose a coiled heat-exchange section immersed in to the reaction sections of Figure 1, however, Haff et al. does disclose a looped capillary tubing wherein the number of loops is directly related to the number of cycles (i.e. time of total amplification reaction) (Columns 13 and 14). Thus, Haff et al. expressly teaches that "looping" the reaction tube can control the period of time a reaction mixture is a certain temperature or series of temperatures. Furthermore, they disclose that the length of tubing is directly related to the residence time of the reaction mixture in each temperature zone, expressly highlighting that tubing of greater length is preferred to achieve better temperature control (column 10, for example).

It would have been *prima facie obvious* to a practitioner of ordinary skill in the art at the time of invention a coiled heat-exchange section immersed into the reaction sections of Figure 1 since Haff suggests such a modification to control residence time of the reaction mixture in each temperature zone.

It is noted that the use of the term "tank" does not patentably distinguish the present invention from the disclosure of Haff et al. even though the present invention appears to be a large-scale amplification apparatus. Furthermore, a practitioner of ordinary skill in the art would have recognized that the apparatus disclosed by Haff et al. could have been "scaled-up" to produce larger amounts of amplification product.

At the time of invention, the disclosure of Haff et al. clearly would have provided the instruction and motivation necessary for one of ordinary skill in the art to practice the methods as claimed. It would have been *prima facie obvious* to one of ordinary skill in the art at the time of invention to practice the instant methods as claimed.

With regard to Claim 6, Haff et al. disclose a heating device containing a pump for circuit-feeding the heat-exchange fluid in between the container body and the heating device, and a heat source for heating the heat-exchange fluid to and retaining it at prescribed temperatures, wherein said heating device supplies the heat-exchange fluid to said container body (Figure 3; Column 14-16). A practitioner of ordinary skill in the art would have recognized that the heating elements above could have been incorporated into the apparatus disclosed in Figure 1 of Haff et al.

With regard to Claims 7 and 9, Haff et al. disclose a *single* continuous reaction tube passing through temperature zones (Figure 1; Column 10, Lines 25-45, for example) and a series of parallel tubes for greater control of reaction parameters (figure 5; columns 16-19, for example)

It would have been *prima facie obvious* to a practitioner of ordinary skill in the art at the time of invention a series of parallel tubes into the reaction sections of Figure 1 since Haff suggests such a modification for greater control of reaction parameters.

With regard to Claims 10-12, Haff et al. disclose that additional baths could be added to increase the number of incubation temperatures (Column 4, Lines 5-10, for example).

### ***Response to Arguments - Claim Rejections - 35 USC § 103***

Applicant's arguments with respect to the previously applied references have been fully considered but they are not persuasive.

Rejection of claim(s) 4-17 over Haff

The crux of Applicant's arguments revolve around the submission that Haff does not provide the motivation to combine to produce a device as now recited, of a unique combination of elements whose synergy leads to the non-obviousness of the present invention.

First, as outlined above, it is submitted that Haff teaches and/or suggests every element of the claimed invention. Thus, the instant invention cannot be thought of as a unique combination of elements.

Second, Applicant appears to submit that the instant invention provides that the combination of elements of the claimed invention provides for a synergistic effect. Applicant is reminded that a *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed invention possesses unexpectedly advantageous or superior properties. Furthermore, the arguments of counsel cannot take the place of evidence in the record. No evidence has been presented by Applicant that would demonstrate that the combination of elements of the claimed invention lead to results that would have been unexpected to a practitioner of ordinary skill in the art at the time of invention.

It is submitted that the claimed invention is merely a "scaled up" version of a well-known chemical process of nucleic acid amplification, the polymerase chain reaction (PCR). As demonstrated by the teachings of Haff, it was well known in the prior art at the time of invention that PCR is amendable to an automated device and/or process. Applicant is directed to, *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)



which held that, "...mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." Applicant is further directed to, *In re Gardner*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), which held that, "...where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device."

Thus, the rejections are maintained.

### ***Conclusion***

**Claims 4, 6, 7, and 9-12 are rejected. No claims are allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

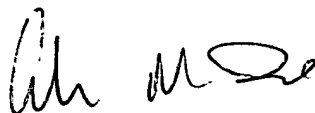
Art Unit: 1637

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

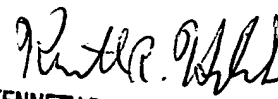
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 8/15/06

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Patent Examiner  
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8/21/06